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(54) Title: CANCER-LINKED GENE AS TARGET FOR CHEMOTHERAPY

(57) Abstract: Cancer-linked gene sequences, and derived amino acid sequences, are disclosed along with processes for assaying potential antitumor agents based on their modulation of the expression of these cancer-linked genes. Also disclosed are antibodies that react with the disclosed polypeptides and methods of using the antibodies to treat cancerous conditions, such as by using the antibody to target cancerous cells *in vivo* for purposes of delivering therapeutic agents thereto. Also described are methods of diagnosing using the gene sequences.



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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/17592

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68

US CL : 435/6

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
MPSRCH

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,914,269 A (BENNETT et al) 22 June 1999 (22.06.1999). See entire document.	1, 3, 5-7, 36



Further documents are listed in the continuation of Box C.



See patent family annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;"

document member of the same patent family

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/17592

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claim Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☐ Claim Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-8 (in-part) and 36

Remark on Protest

☐  
☐

The additional search fees were accompanied by the applicant's protest.  
No protest accompanied the payment of additional search fees.

**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.  
Group 1, Claims 1-8, 36, drawn to a method for identifying an agent that modulates the activity of the polynucleotide of SEQ ID NO:1.

Groups 2-4, Claims 1-8, 36, drawn to a method for identifying an agent that modulates the activity of the polynucleotide of SEQ ID NO:2-4.

Group 5, Claims 9-10, drawn to a method for determining the cancerous status of a cell, comprising detecting an elevated level of expression of the polynucleotide of SEQ ID NO: 1.

Groups 6-8, Claims 9-10, drawn to a method for determining the cancerous status of a cell, comprising detecting an elevated level of expression of the polynucleotide of SEQ ID NO: 2-4.

Groups 9-10, Claims 11-12, 27-28, drawn to the polypeptide of SEQ ID NO:5-6.

Groups 11-12, Claims 13-23, drawn to an antibody that reacts with the polypeptide of SEQ ID NO:5-6.

Groups 13-16, Claims 24-26, 29, 32-33, drawn to a method for treating cancer, using an agent that modulates the expression or activity of the polynucleotide of SEQ ID NO:1-4.

Groups 17-18, claims 30-31, 34-35, drawn to a method for treating cancer, using the polypeptide of SEQ ID NO:5-6.

The inventions listed as Groups 1-18 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group I, claims 1-8, 36 form a single general inventive concept.

Groups 2-4, 6-8, 14-18 are not linked to the single general inventive concept of group 1, because the methods of groups 2-4, 6-8, 14-18 do not use the polynucleotide of SEQ ID NO:1 of group 1.

Groups 5, 13 are additional use claimed for SEQ ID NO:1.

Groups 9-12 are not linked to the single general inventive concept of group 1, because polypeptides of groups 9-10, and the antibodies of groups 11-12 do not share a common structure with the polynucleotide of SEQ ID NO: 1 of group 1.